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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,957	04/05/2004	Connie Li Sun	034536-1209	2282

22428 7590 03/04/2005

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
SHIAO, REI TSANG	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 03/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/816,957	SUN ET AL.	
	Examiner	Art Unit	
	Robert Shiao	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *responses filed on 12/22/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *16-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/05/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This application claims benefit of the provisional application: 60/282,630 with a filing date 04/09/2001.

2. Claims 1-34 are pending in the application.

Responses to Election/Restriction

3. Applicant's election with traverse of Group I claims 1-15, in part, in the reply filed on December 22, 2004, is acknowledged. The traversal is on the grounds that the Examiner has not established that search and examination of the entire application as filed constitutes an undue burden. This is not found persuasive, and the reasons are given, *infra*.

Status of the Claims

4. Claims 1-34 are pending in the application. The scope of the invention of the elected subject matter is as follows:

Claims 1-15, in part, drawn to compounds/compositions of formula (I), wherein the variables R^1, R^2, R^3, R^4, and R^6 independently does not represent heteroaryl or heterocycle, the variables R^1, R^2, R^3, R^4, and R^6 independently is not substituted with heteroaryl or heterocycle, i.e., R^{15} and R^{16} do not form heterocycloamino, the variable R^5 is as defined in claim 1.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and

composition from the compounds of the elected invention. The withdrawn compounds contain varying functional groups (i.e., heteroaryl or heterocycloalkyl of the variable R^1, R^5, or R^2) which differ from those of the elected invention such as oxazole, diazole, pyridine, morpholine, etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e., class 548 subclass 215(+) (oxazole), class 548 subclass 300.1(+) (diazole), class 546 subclass 249 (+) (pyridine), class 544 subclass 106(+) (morpholine), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly.

The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

Claims 1-15, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 1-15, in part, <u>not</u> embraced in above elected subject matter, and claims 16-34 are withdrawn from further consideration pursuant to

37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It is noted that the claims contain subject matter "preventing" and "protein kinase related disorder", which were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, see claim 5, line 1.

6. Claims 5-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating diabetes using a compound of formula (I), does not reasonably provide enablement a method of preventing or treating CNS diseases using a compound of formula (I), see Monse et al. CAS:141:38635. Monse et al. disclose a compound of formula (I) or (II) as protein

kinase inhibitors as agents treating CNS diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1988):

1) Nature of invention.

2) State of prior art.

3) Level of ordinary skill in the art.

4) Level of predictability in the art.

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention

The claims are drawn to a method of use of formula (I) without limitation of "preventing disease" or "protein kinase related disorder".

2) State of the prior art

The reference Spada et al. US 5,302,606 does not indicate which compounds of instant compounds may be useful in the claimed invention. Spada et al. '606 is pertaining to stryl-substituted pyridyl compounds which inhibit EGF receptor tyrosine kinase.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The claims are drawn to a method of use of formula (I) without limitation of "preventing disease" or "protein kinase related disorder". Applicant's specification does not enable the public to prepare such "a method of use of formula (I) without limitation of "preventing disease" or "protein kinase related disorder"" by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The claims are drawn to a method of use of formula (I) without limitation of "preventing disease" or "protein kinase related disorder", see claim 5, line 1. Different types of the genus of methods require various experimental procedures and without guidance that is applicable to all possible "a method of use of formula (I) without limitation of "preventing disease" or "protein kinase related disorder"", there would be little predictability in the scope of claimed methods.

5) Amount of direction and guidance provided by the inventor.

The claims are drawn to a method of use of formula (I) without limitation of "preventing disease" or "protein kinase related disorder"", encompasses a vast number of methods. Applicant's limited guidance does not enable the public to prepare such "a method of use of formula (I) without limitation of "preventing disease" or "protein kinase related disorder"" in the specification. There is no enablement for "a method of use of formula (I) without limitation of "preventing disease" or "protein kinase related disorder"", i.e., a compound of formula (I) is used for preventing or treating CNS diseases, which are neither enabled nor supported in the specification.

6) Existence of working examples.

The claims are drawn to a method of use of formula (I) without limitation of "preventing disease" or "protein kinase related disorder", encompasses a vast number of methods. Applicant's limited working examples do not enable the public to prepare such a numerous amount of "a method of use of formula (I) without limitation of "preventing disease" or "protein kinase related disorder"", in the specification. Applicants claim "a method of use of formula (I) without limitation of "preventing disease" or "protein kinase related disorder"", however, the specification provides only limited examples of methods.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible "a method of use of formula (I) without limitation of "preventing disease" or "protein kinase related disorder"".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous methods in order to obtain "a method of use of formula (I) without limitation of

"preventing disease" or "protein kinase related disorder"" as claimed. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed compounds without undue experimentation, see In re Armbruster 185 USPQ 152 CCPA 1975. Elimination the limitation "preventing" of claim 5, and incorporation of the limitation "protein kinase related disorder" into claims 5 and 7, i.e., the named diseases of claim 8 or 9, would obviate the rejection.

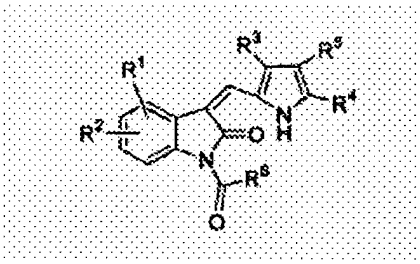
Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

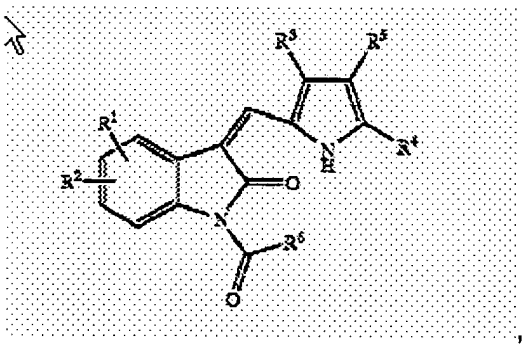
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-15 re rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 and 5 of Sun et al. US 6,797,725. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim a compound/compositions of formula (I) as agents treating cancer,  . The compounds are found on the pages 3-20 of the specification.

Sun et al. claim a compound/compositions of formula (I) as agents treating cancer,

 , wherein the variable R^5 represents $-COR^{10}$, R^{10} represents $-NR^{11}R^{12}$, where R^{11} represents hydrogen or alkyl, R^{12} represents aminoalkyl optionally substituted with one or two hydroxyl group. Variables R^1, R^2, R^3,

and R^4 independently hydrogen, alkyl, or halo, and variable R^6 independently represents $-OR^{13}$ or $-NR^{15}R^{16}$. A number of examples have been specifically exemplified, see columns 115-116, and 37-38.

The difference between the instant claims and Sun et al. is that the limitation of instant variable R^5 of formula (I) are species of Sun et al. R^5 at the same position.

One having ordinary skill in the art would find the claims 1-15 prima facie obvious because one would be motivated to employ the compounds/compositions of Sun et al. to obtain instant compounds/compositions of formula (I), wherein the variables R^1, R^2, R^3, R^4, and R^6 independently does not represent heteroaryl or heterocycle, the variables R^1, R^2, R^3, R^4, and R^6 independently is not substituted with heteroaryl or heterocycle, i.e., R^{15} and R^{16} do not form heterocycloamino, the variable R^5 is as defined in claim 1.

The motivation to make the claimed compounds derives from the expectation that the instant claimed compounds/compositions would possess similar activities, i.e., agents treating cancer, from the known Sun et al. compounds to that which is claimed in the reference.

Objection

9. Claims 1-15 are objected to as containing non-elected subject matter hetroaryl, heterocycle, heterocycloamino, heterocyclylalkyl, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the pages 2-3 *supra*.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707.

The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita Desai
Primary Patent Examiner
Technical Center 1600
Tel: (571) 272-0684

R.S.

Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

March 02, 2005

RDesai 3/2/05.